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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,954	10/09/2006	Brian David Owen Owen-Smith	133088.00701(P37166US)	1704
35151	7590	08/31/2009		
Pepper Hamilton LLP 400 Berwyn Park 899 Cassatt Road Berwyn, PA 19312-1183			EXAMINER GOUGH, TIFFANY MAUREEN	
			ART UNIT 1657	PAPER NUMBER
			MAIL DATE 08/31/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/560,954	Applicant(s) OWEN-SMITH, BRIAN DAVID OWEN	
	Examiner TIFFANY M. GOUGH	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/15/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response filed 4/15/2009 has been received and entered into the case.

Claims 1,3-5 are pending and have been considered on the merits. All arguments and amendments have been considered. Applicants Declaration filed on 4/15/2009 has been received, entered and considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,3-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 requires the sample be processed and assayed, however, it is not clear how the sample is processed or assayed as there are no actual processing and assaying steps claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of each of WO 00/08207, Lee (US 6753159), and Fossati et al. (Clin. Chem, 1980) in view of Owen-Smith et al. (The Lancet, 1998) and Owen-Smith (Salivary Urate as an indicator of metabolic stress, 1981) in further view of each of Dunlop et al (Brit. Med. Journal, 1978) and Schuster et al. (Gynecol. Obstet. Invest., 1981) and Pipkin (Journal of Hypertension, 2004, p.237-239).

Applicant claims a kit and equipment comprising reagents for determining the level of urate in a biological sample. Also claimed is a method for diagnosing pre-eclampsia comprising measuring urate in maternal saliva.

As stated above each of WO'207, US 6753159 and Fossati teach a method, kit and equipment comprising uricase and 3,5-dichloro-2-hydroxybenzenesulfonic acid and 4-aminophenazone for determining the level of urate in a biological sample.

The references do not teach measuring levels of urate in saliva.

Owen-Smith teach a method, kit and equipment comprising the uricase colorimetric method for determining the level of urate in a biological sample, specifically saliva.

Owen-Smith, 1981 teach that salivary urate is an indicator of pre-eclampsia and that non-invasive monitoring of salivary urate may help management of pre-eclampsia.

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Thus, while measuring urate levels in biological fluids has long been known to be useful in diagnosing pre-eclampsia, the above art additionally teaches that urate levels can be measured in saliva. the art additionally teaches that salivary urate can be measured and used for diagnosing pre-eclampsia. Therefore, known methods of measuring urate in biological fluids such as timed end point, dry test and dip stick methods would be obvious to use in a method of measuring urate from a biological fluid such as saliva to diagnose pre-eclampsia.

At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to have measured urate levels in maternal saliva in a method for diagnosing preeclampsia because the art teaches that there is a clear association between urate concentration levels and pre-eclampsia. Further, the art teaches that urate is widely distributed in extracellular fluid such as saliva. Thus, it would be obvious to one of ordinary skill in the art to use saliva as the biological fluid in the methods of WO 00/08207, Lee (US 6753159), or Fossati.

The references have been relied upon to show that urate in general is known to be associated with preeclampsia. Methods of detecting urate in biological fluids to diagnose preeclampsia are also known. The art additionally teaches that saliva is a known source of urate and can be used in methods of measuring urate to diagnose preeclampsia.

Therefore, the invention as whole is prima facie obvious over the prior art.

Response to Arguments

Applicant's arguments with respect to claim 1,3-5 have been considered but are moot in view of the new ground(s) of rejection. Applicants arguments regarding an obstetrician versus a rheumatologist are interesting yet not convincing and not commensurate in scope with the claimed invention. The Declaration of Mr. Hooker has also been considered but is not found to be substantial nor persuasive. Applicant also argues the difference between plasma and saliva, however it is interesting to note that applicants specification p. 3 sections 0014 and 0015 teach that blood or plasma may also be used in the claimed invention. Applicants arguments regarding men vs. women and gout vs. preeclampsia, and day/night variation in salivary levels of urate have also been considered and while interesting are not commensurate in scope with the claimed invention.

Conclusion

NO claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIFFANY M. GOUGH whose telephone number is (571)272-0697. The examiner can normally be reached on M-F 8-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ralph Gitomer/
Primary Examiner, Art Unit 1657

/Tiffany M Gough/
Examiner, Art Unit 1657
/David M. Naff/
Primary Examiner, Art Unit 1657